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PATENT  
Attorney Docket No. LEX-023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies *et al.*  
SERIAL NO.: 10/737,208 GROUP NO.: 1647  
FILING DATE: December 16, 2003 EXAMINER: Galvez, James Jason  
TITLE: Immunocytokine Sequences And Uses Thereof

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the non-U.S. patent documents and non-patent publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) above but before the mailing date of any of a **final action** under 37 C.F.R. 1.113, a **notice of allowance** under 37 C.F.R. 1.311, or an action that otherwise closes prosecution in the application, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein; or
- ☐ (3) after the period defined in (2) above but before the payment of the **issue fee**, **AND**

- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe that no petition or fee is required for entry and consideration of this paper. If any petition or fee is required, please consider this a conditional petition for any required extension of time, and a conditional authorization to charge any required fee to Deposit Account No. 50-1721.

Date: May 11, 2005  
Reg. No. 51,551

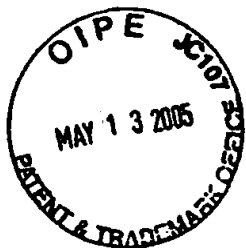
Tel. No.: (617) 261-3198  
Fax No.: (617) 261-3175

Respectfully submitted,



Fangli Chen  
Atty/Agent for Applicant(s)  
Kirkpatrick & Lockhart Nicholson  
Graham LLP  
75 State Street  
Boston, Massachusetts 02109-1808

844719



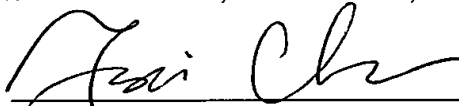
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Attorney Docket No. LEX-023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies et al.  
SERIAL NO.: 10/737,208 GROUP NO.: 1647  
FILING DATE: December 16, 2003 EXAMINER: Galvez, James Jason  
TITLE: Immunocytokine Sequences And Uses Thereof

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 11<sup>th</sup> day of May, 2005.

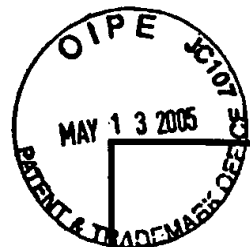
  
Fangli Chen

Mail Stop Amendment  
Commissioner for Patents  
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Sir:

Submitted herewith is/are:

1. Transmittal Form (1 pg.);
2. Supplemental Information Disclosure Statement (2 pgs.);
3. PTO Form 1449 (12 pgs.);
4. Cited references B108-B119 and C262-C428); and
5. Return Receipt Postcard.



# TRANSMITTAL FORM

Application Serial Number	10/737,208
Filing Date	December 16, 2003
First Named Inventor	Gillies
Group Art Unit	1647
Examiner Name	Galvez, James Jason
Attorney Docket No.	LEX-023
Patent No.	Not applicable
Issue Date	Not applicable

## ENCLOSURES (check all that apply)

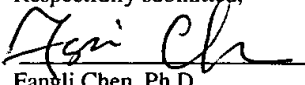
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| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Check Attached<br><input type="checkbox"/> Copy of Fee Transmittal Form<br><br><input type="checkbox"/> Amendment/Response<br><input type="checkbox"/> Preliminary<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets <u>  </u> ]<br><br><input type="checkbox"/> Petition for Extension of Time<br><br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input checked="" type="checkbox"/> Form PTO-1449<br><input checked="" type="checkbox"/> Copies of IDS Citations (B108-B119 and C262-C428)<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><br><input type="checkbox"/> Sequence Listing submission<br><input type="checkbox"/> Paper Copy/CD<br><input type="checkbox"/> Computer Readable Copy<br><input type="checkbox"/> Statement verifying identity of above | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application<br><br><input type="checkbox"/> Formal Drawing(s)<br><br><input type="checkbox"/> Request For Continued Examination (RCE) Transmittal<br><br><input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)<br><br><input type="checkbox"/> Terminal Disclaimer<br><br><input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application<br><input type="checkbox"/> Small Entity Statement<br><br><input type="checkbox"/> CD(s) for large table or computer program<br><br><input type="checkbox"/> Amendment After Allowance<br><br><input type="checkbox"/> Request for Certificate of Correction<br><input type="checkbox"/> Certificate of Correction (in duplicate) | <input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences<br><br><input type="checkbox"/> Appeal Brief (in triplicate)<br><br><input type="checkbox"/> Status Inquiry<br><br><input checked="" type="checkbox"/> Return Receipt Postcard<br><input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8<br><br><input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8<br><br><input type="checkbox"/> Additional Enclosure(s) (please identify below) |
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## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
Kirkpatrick & Lockhart Nicholson  
Graham LLP  
75 State Street  
Boston, MA 02109-1808  
Tel. No.: (617) 261-3100  
Fax No.: (617) 261-3175

## SIGNATURE BLOCK

Date: May 11, 2005  
Reg. No. 51,551  
Tel. No.: (617) 261-3198  
Fax No.: (617) 261-3175

Respectfully submitted,  
  
Fangli Chen, Ph.D.  
Agent for Applicant  
Kirkpatrick & Lockhart Nicholson  
Graham LLP  
75 State Street  
Boston, MA 02109-1808

FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT

ATTORNEY DOCKET NO.: LEX-023

APPLICANT(S): Gillies *et al.*

SERIAL NO.: 10/737,208

CONF. NO.: 6855

FILING DATE: December 16, 2003 GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUME NT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A114	4,522,811	6/1/85	Eppstein <i>et al.</i>			
	A115	4,667,016	5/19/87	Lai <i>et al.</i>			
	A116	4,732,683	3/22/88	Georgiades <i>et al.</i>			
	A117	4,737,462	4/12/88	Mark <i>et al.</i>			
	A118	4,975,369	12/4/90	Beavers <i>et al.</i>			
	A119	5,082,658	1/21/92	Palladino			
	A120	5,091,513	2/25/92	Huston <i>et al.</i>			
	A121	5,399,346	3/21/95	Anderson <i>et al.</i>			
	A122	5,428,130	6/27/95	Capon <i>et al.</i>			
	A123	5,480,981	1/2/96	Goodwin <i>et al.</i>			
	A124	5,589,466	12/31/96	Felgner <i>et al.</i>			
	A125	5,614,184	3/25/97	Sytkowski <i>et al.</i>			
	A126	5,712,120	1/27/98	Rodriguez <i>et al.</i>			
	A127	5,738,852	4/14/98	Robinson <i>et al.</i>			
	A128	5,795,779	8/18/98	McCormick			
	A129	5,827,703	10/27/98	Debs <i>et al.</i>			
	A130	5,837,821	11/17/98	Wu <i>et al.</i>			
	A131	6,281,010	8/28/01	Gao <i>et al.</i>			
	A132	6,291,158	9/18/01	Winter <i>et al.</i>			
	A133	6,627,615	9/30/03	Debs <i>et al.</i>			

EXAMINER

DATE CONSIDERED

<b>FORM PTO - 1449</b>					<b>ATTORNEY DOCKET NO.: LEX-023</b>				
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>					<b>APPLICANT(S): Gillies <i>et al.</i></b>				
					<b>SERIAL NO.: 10/737,208</b>		<b>CONF. NO.: 6855</b>		
					<b>FILING DATE: December 16, 2003 GROUP: 1647</b>				
<b>FOREIGN PATENT DOCUMENTS</b>									
<b>EXAM INIT.</b>		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTR Y CODE</b>	<b>CLASS</b>	<b>SUB CLAS S</b>	<b>FILING DATE</b>	<b>ABSTRAC T ONLY</b>	<b>ENGLISH LANG (Y/N)</b>
	B108	0 428 267 B1	12/11/96	EP					Y
	B109	0 428 596 B1	4/17/96	EP					Y
	B110	0 433 827 B1	3/4/98	EP					Y
	B111	0 519 596 A1	12/23/92	EP					Y
	B112	0 668 351 B1	9/22/99	EP					Y
	B113	0 699 755 A2	3/6/96	EP					Y
	B114	2 188 638	10/7/87	GB					Y
	B115	WO 92/10755	6/25/92	PCT					Y
	B116	WO 94/25609	11/10/94	PCT					Y
	B117	WO 96/40792	12/19/96	PCT					Y
	B118	WO 00/01822	1/13/00	PCT					Y
	B119	WO 02/074783	9/26/02	PCT					Y

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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		FILING DATE: December 16, 2003      GROUP: 1647
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C262	Aichele <i>et al.</i> , (1994), "Peptide-Induced T-Cell Tolerance to Prevent Autoimmune Diabetes in a Transgenic Mouse Model," <u>Proc. Natl. Acad. Sci. USA</u> , 91:444-448.
	C263	Altschul <i>et al.</i> , (1990), "Basic Local Alignment Search Tool," <u>J. Mol. Biol.</u> , 215:403-10.
	C264	Altschul <i>et al.</i> , (1997), "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs," <u>Nucleic Acids Res.</u> , 25(17):3389-3402.
	C265	Anderson <i>et al.</i> , (1980), "Characterization of the Fc Receptor for IgG on a Human Macrophage Cell Line U937," <u>J. Immunol.</u> , 125(6):2735-41.
	C266	Anderson <i>et al.</i> , (1994), "Effects of Route and Formulation on Clinical Pharmacokinetics of Interleukin-2," <u>Clin. Pharmacokinet.</u> , 27(1):19-31.
	C267	Baici <i>et al.</i> , (1980), "Kinetics of the Different Susceptibilities of the Four Human Immunoglobulin G Subclasses to Proteolysis by Human Lysosomal Elastase," <u>Scand. J. Immunol.</u> 12(1):41-50.
	C268	Barbulescu <i>et al.</i> , (1998), "IL-12 and IL-18 Differentially Regulate the Transcriptional Activity of the Human IFN- $\gamma$ Promoter in Primary CD4+ T Lymphocytes," <u>J. Immunol.</u> , 160:3642-7.
	C269	Bednarek <i>et al.</i> , (1991), "Soluble HLA-A2.1 Restricted Peptides that are Recognized by Influenza Virus Specific Cytotoxic T Lymphocytes," <u>J. Immunol. Methods</u> , 139:41-47.
	C270	Benacerraf <i>et al.</i> , (1959), "The Clearance of Antigen Antibody Complexes from the Blood by the Reticulo-Endothelial System," <u>J. Immunol.</u> , 82:131-7.
	C271	Böhm, (1994), "On the Use of LUDI to Search the Fine Chemicals Directory for Ligands of Proteins of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8:623-32.
	C272	Böhm, (1994), "The Development of a Simple Empirical Scoring Function to Estimate the Binding Constant for a Protein-Ligand Complex of Known Three-Dimensional Structure," <u>J. Comput. Aided Mol. Des.</u> , 8(3):243-56.
	C273	Böhm, (1998), "Prediction of Binding Constants of Protein Ligands: A Fast Method for the Prioritization of Hits Obtained from De Novo Design or 3D Database Search Programs," <u>J. Comput. Aided Mol. Des.</u> , 12(4):309-23.
	C274	Boshart <i>et al.</i> , (1985), "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <u>Cell</u> , 41:521-530.
	C275	Boulianne <i>et al.</i> , (1984), "Production of Functional Chimaeric Mouse/Human Antibody," <u>Nature</u> , 312:643-6.
	C276	Bourgeois <i>et al.</i> , (1974), "Determination of the Primary Structure of a Mouse IgG2a Immunoglobulin Amino Acid Sequence of the Fc Fragment: Implications for the Evolution of Immunoglobulin Structure and Function," <u>Eur. J. Biochem.</u> , 43:423-35.
	C277	Brambell <i>et al.</i> , (1964), "A Theoretical Model of $\gamma$ -Globulin Catabolism," <u>Nature</u> , 203:1352-55.
	C278	Brazolot Millan <i>et al.</i> , (1998), "Cpg DNA Can Induce Strong TH1 Humoral and Cell-Mediated Immune Responses against Hepatitis B Surface Antigen in Young Mice," <u>Proc. Natl. Acad. Sci. USA</u> , 95:15553-8.

EXAMINER	DATE CONSIDERED
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<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>		ATTORNEY DOCKET NO.: LEX-023 APPLICANT(S): Gillies <i>et al.</i> SERIAL NO.: 10/737,208      CONF. NO.: 6855 FILING DATE: December 16, 2003      GROUP: 1647	
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>		
	C279	Brekke <i>et al.</i> , (1994), "Human IgG Isotype-Specific Amino Acid Residues Affecting Complement-Mediated Cell Lysis and Phagocytosis," <u>Eur. J. Immunol.</u> , 24:2542-2547.	
	C280	Brem <i>et al.</i> , (1993), "The Combination of Antiangiogenic Agents to Inhibit Primary Tumor Growth and Metastasis," <u>J. Pediatr. Surg.</u> , 28(10):1253-7.	
	C281	Brocklebank <i>et al.</i> , (2001), "Enumeration of CD34+ Cells in Cord Blood: A Variation on a Single-Platform Flow Cytometric Method Based on the ISHAGE Gating Strategy," <u>Cytometry</u> , 46:254-261	
	C282	Brooks <i>et al.</i> , (1983), "CHARMM: A Program for Macromolecular Energy Minimization and Dynamics Calculations," <u>J. Comput. Chemistry</u> , 4:187-217.	
	C283	Broudy <i>et al.</i> , (1988), "Recombinant Human Erythropoietin: Purification and Analysis of Carbohydrate Linkage," <u>Arch. Biochem. Biophys.</u> , 265:329-36.	
	C284	Bubenik <i>et al.</i> , (1995), "Interleukin-2 Gene Therapy of Residual EL-4 Leukaemia Potentiates the Effect of Cyclophosphamide Pretreatment," <u>J. Cancer Res. Clin. Oncol.</u> , 121:39-43.	
	C285	Bumol <i>et al.</i> , (1982), "Unique Glycoprotein-Proteoglycan Complex Defined by Monoclonal Antibody on Human Melanoma Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 79:1245-9.	
	C286	Carnemolla <i>et al.</i> , (1989), "A Tumor-Associated Fibronectin Isoform Generated by Alternative Splicing of Messenger RNA Precursors," <u>J. Cell. Biol.</u> , 108:1139-1148.	
	C287	Carnemolla <i>et al.</i> , (1992), "The Inclusion of the Type III Repeat ED-B in the Fibronectin Molecule Generates Conformational Modifications that Unmask a Cryptic Sequence," <u>J. Biol. Chem.</u> , 267(34):24689-24692.	
	C288	Casadevall, <i>et al.</i> , (2002) "Pure Red-Cell Aplasia and Antierythropoietin Antibodies in Patients Treated with Recombinant Erythropoietin," <u>The New Eng. School of Medicine</u> , 346:469-75.	
	C289	Cazzola <i>et al.</i> , (1998), "Red Blood Cell Precursor Mass as an Independent Determinant of Serum Erythropoietin Level," <u>Blood</u> , 91:2139-45.	
	C290	Chan <i>et al.</i> , (1992), "Mechanisms of IFN- $\gamma$ Induction by Natural Killer Cell Stimulatory Factor (NKSF/IL-12). Role of Transcription and mRNA Stability in the Synergistic Interaction Between NKSF and IL-2," <u>J. Immunol.</u> , 148:92-98.	
	C291	Chappel <i>et al.</i> , (1991), "Identification of the Fc Gamma Receptor Class I Binding Site In Human IgG Through Use of Recombinant IgG1/IgG2 Hybrid and Point-Mutated Antibodies," <u>Proc. Natl. Acad. Sci. USA</u> , 88(20):9036-40.	
	C292	Cheetham, (1998), "NMR Structure of Human Erythropoietin and a Comparison with its Receptor Bound Conformation," <u>Nat. Struct. Biol.</u> , 5:861-6.	
	C293	Ciardiello <i>et al.</i> , (1996), "Antitumor Activity of Combined Blockade of Epidermal Growth Factor Receptor and Protein Kinase A," <u>J. Natl. Cancer Inst.</u> , 88:1770-6.	
	C294	Cirulli <i>et al.</i> , (1998), "KSA Antigen Ep-CAM Mediates Cell-Cell Adhesion of Pancreatic Epithelial Cells: Morphoregulatory Roles in Pancreatic Islet Development," <u>J. Cell Biol.</u> , 140:1519-34.	
	C295	Cohen <i>et al.</i> , (1998), "An Artificial Cell-Cycle Inhibitor Isolated from a Combinatorial Library," <u>Proc. Natl. Acad. Sci. USA</u> , 95:14272-7.	

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	C296	Congote <i>et al.</i> , (1984), The Erthrotropins, New Erythroid Cell Stimulate Factors Extracted From Human and Bovine Fetal Tissues," Abstract 364, "Proceedings 7 <sup>th</sup> Intl. Congress of Endocrinology," Quebec City, Quebec, July 1-7, 1984.
	C297	Congote, (1983), "Isolation of Two Biologically Active Peptides, Erythrotropin I and Erythrotropin II from Fetal Calf Intestine," <u>Biochem. Biophys. Res. Commun.</u> , 115(2):477-83.
	C298	Congote, (1984), "Extraction from Fetal Bovine Serum of Erythrotropin, an Erythroid Cell-Stimulating Factor," <u>Anal. Biochem.</u> , 140:428-33.
	C299	Connor <i>et al.</i> , (2004), "Ex vivo Evaluation of Anti-EpCAM Immunocytokine huKS-IL2 in Ovarian Cancer," <u>J. Immunotherapy</u> , 27:211-219.
	C300	Cosenza <i>et al.</i> , (1997), "Disulfide Bond Assignment in Human Interleukin-7 by Matrix-Assisted Laser Desorption/Ionization Mass Spectroscopy and Site-Directed Cysteine to Serine Mutational Analysis," <u>J. Biol. Chem.</u> , 272:32995-3000.
	C301	Cunningham <i>et al.</i> , (1989), "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," <u>Science</u> , 244:1081-85.
	C302	Curiel <i>et al.</i> , (1991), "Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery," <u>Proc. Natl. Acad. Sci. USA</u> , 88:8850-4.
	C303	Dauber-Osguthorpe <i>et al.</i> , (1988), "Structure and Energetics of Ligand Binding to Proteins: Escherichia Coli Dihydrofolate Reductase-Trimethoprim, A Drug-Receptor System," <u>Proteins</u> , 4:31-47.
	C304	Daugherty <i>et al.</i> , (1991), "Polymerase Chain Reaction Facilitates the Cloning, CDR-Grafting, and Rapid Expression of a Murine Monoclonal Antibody Directed Against the CD18 Component of Leukocyte Integrins," <u>Nucleic Acid Res.</u> , 19:2471-2476.
	C305	De Bruijn <i>et al.</i> , (1995), "Phagocyte-Induced Antigen-Specific Activation of Unprimed CD8+ T Cells in Vitro," <u>Eur. J. Immunol.</u> , 25:1274-85.
	C306	Delorme <i>et al.</i> , (1992), "Role of Glycosylation on the Secretion and Biological Activity of Erythropoietin," <u>Biochemistry</u> , 31:9871-6.
	C307	Desai <i>et al.</i> , (1992), "IL-12 Receptor. II. Distribution and Regulation of Receptor Expression," <u>J. Immunol.</u> , 148:3125-32.
	C308	Dillman <i>et al.</i> , (1994), "Human Anti-Mouse Antibody Response in Cancer Patients Following Single Low-Dose Injections of Radiolabeled Murine Monoclonal Antibodies," <u>Cancer Biotherapy</u> , 9:17-28.
	C309	Donnelly <i>et al.</i> , (1993), "Targeted Delivery of Peptide Epitopes to Class I Major Histocompatibility Molecules by a Modified Pseudomonas Exotoxin," <u>Proc. Natl. Acad. Sci. USA</u> , 90:3530-4.
	C310	Donnelly <i>et al.</i> , (1997), "DNA Vaccines," <u>Annu. Rev. Immunol.</u> , 15:617-48.
	C311	Dube <i>et al.</i> , (1988), "Glycosylation at Specific Sites of Erythropoietin is Essential for Biosynthesis, Secretion, and Biological Function," <u>J. Biol. Chem.</u> , 263:17516-21.
	C312	Ellison <i>et al.</i> , (1982), "The Nucleotide Sequence of a Human Immunoglobulin C $\gamma_1$ Gene," <u>Nucleic Acids Res.</u> , 10:4071-9.

EXAMINER	DATE CONSIDERED
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	C313	Faas <i>et al.</i> , (1993), "Phenotypically Diverse Mouse Thymic Stromal Cell Lines which Induce Proliferation and Differentiation Of Hematopoietic Cells," <u>Eur. J. Immunol.</u> , 23:1201-14.
	C314	Farner <i>et al.</i> , (1995), "Distinction Between $\gamma_c$ C Detection and Function in YT Lymphoid Cells and in the Granulocyte-Macrophage Colony-Stimulating Factor-Responsive Human Myeloid Cell Line, Tf-1," <u>Blood</u> , 86:4568-78.
	C315	Fawell <i>et al.</i> , (1994), "Tat-Mediated Delivery of Heterologous Proteins into Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 91:664-8.
	C316	Fu <i>et al.</i> , (1993), "The Sheep Erythropoietin Gene: Molecular Cloning and Effect of Hemorrhage on Plasma Erythropoietin and Renal/Liver Messenger RNA in Adult Sheep," <u>Mol. Cell. Endocrinol.</u> , 93:107-16.
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		FILING DATE: December 16, 2003      GROUP: 1647
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<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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